

Marked Up Version of Amended Claims Pursuant to 37 CFR 121(c)(1)(ii)

(Amended) 1. A substantially pure antibody or antibody fragment specific for [the] an initial peptide sequence of amino acids 1 to 7, (SEQ. ID NO. 1), for whole parathyroid hormone which comprises a domain for adenylate cyclase activation [, VAL-SER-GLU-ILE-GLN-LEU-MET (SEQ ID No. 1)], wherein at least four amino acids in this sequence are part of [the] a reactive portion with the antibody.

(Amended) 4. A method for measuring the amount of whole parathyroid hormone in a sample comprising:

- d) adding to the sample a first labeled antibody or antibody fragment specific for [the]an initial peptide sequence of amino acids 1 to 7, (SEQ. ID NO. 1), for whole parathyroid hormone which comprises a domain for adenylate cyclase activation [, VAL-SER-GLU-ILE-GLN-LEU-MET (SEQ ID No. 1)], wherein at least four amino acids in this sequence are part of [the] an antibody reactive portion of the peptide, in an amount sufficient to bind all whole parathyroid hormone present;
- e) allowing the labeled antibody to bind to any whole parathyroid hormone present, thereby forming a complex; and
- f) measuring the amount of labeled complex, and thereby determining the amount of whole parathyroid hormone.

(Amended) 5. The method of Claim 4 wherein the labeled anti-parathyroid hormone antibody or antibody fragment is a monoclonal antibody.

(Amended) 6. The method of Claim 4 wherein the labeled anti-parathyroid hormone antibody or antibody fragment is a polyclonal antibody.

(Amended) 7. The method of Claim 4 wherein a second antibody is added which is bound to a solid support and specifically binds to a portion of [wPTH] whole parathyroid hormone other than the initial peptide sequence which binds to the first antibody.

(Amended) 10. The method of Claim 4 wherein the label or signal generating component of the first antibody is selected from the group consisting of chemiluminescent agents, colorimetric agents, energy transfer agents, enzymes, fluorescent agents, and radioisotopes.

(Amended) 11. The method of Claim 7 also comprising adding to the sample a third antibody specific for [the C-terminal portion of] any parathyroid hormone C-terminal fragment present in the sample, but which is not reactive to the initial peptide sequence, [is added to the sample] thereby [reduce] reducing binding reaction interference from any parathyroid hormone C-terminal fragments present in the sample.

(Amended) 12. A method for measuring the amount of whole parathyroid hormone in a sample comprising:

- e) adding to the sample a first antibody or antibody fragment specific for [the] an initial peptide sequence of amino acids 1 to 7, (SEQ. ID NO. 1), for whole parathyroid hormone which comprises a domain for adenylate cyclase activation [, VAL-SER-GLU-ILE-GLN-LEU-MET (SEQ ID No. 1)], wherein at least four amino acids in this sequence are part of [the] an antibody reactive portion of the peptide, in an amount sufficient to bind all whole parathyroid hormone present;
- f) allowing the first antibody to bind to any whole parathyroid hormone present, thereby forming a complex;
- g) labeling the complex by means of adding a second antibody that has a label or signal generating component attached thereto and that specifically binds to a portion of whole parathyroid hormone [PTH] other than the initial peptide sequence which binds to the

first antibody; and

- h) measuring the amount of labeled complex, and thereby determining the amount of whole parathyroid hormone.

(Amended) 15. The method of Claim 12 wherein the second labeled antibody binds either to [the] a mid-portion of whole parathyroid hormone [PTH] or the C-terminal of whole parathyroid hormone [PTH] and also comprising adding at least a third antibody which specifically binds to the first antibody [an epitope left open after PTH binds to the first antibody and the second antibody], thereby forming a precipitating mass.

(Amended) 16. The method of Claim 15 wherein the [C-terminal] third antibody is bound to a solid support.

(Amended) 17. A method for measuring whole parathyroid hormone by means of a precipitating or turbidometric immunoassay comprising:

- d) adding to a sample an antibody or antibody fragment specific for [the] an initial peptide sequence of amino acids 1 to 7, (SEQ. ID NO. 1), for whole parathyroid hormone which comprises a domain for adenylate cyclase activation [, VAL-SER-GLU-ILE-GLN-LEU-MET (SEQ ID No. 1)], wherein at least four amino acids in this sequence are part of [the] an antibody reactive portion of the peptide, in an amount sufficient to bind all whole parathyroid hormone present, said antibody being attached to a colloidal particle or moiety which can be used to detect a signal change;
- e) allowing the antibody to bind to any whole parathyroid hormone present, thereby forming a complex; and
- f) measuring the change in signal due to the formation of the complex, and thereby determining the amount of whole parathyroid hormone.

(Amended) 18. A kit containing reagents for performing an assay for whole parathyroid hormone comprising:

- c) a first substantially pure antibody or antibody fragment specific for [the] an initial sequence of amino acids 1 to 7, (SEQ. ID NO. 1), of whole parathyroid hormone which comprises a domain for adenylate cyclase activation [, VAL-SER-GLU-ILE-GLN-LEU-MET (SEQ ID No. 1)], wherein at least four amino acids in this sequence are part of [the] an antibody reactive portion of the peptide; and
- d) a labeling component that binds to whole parathyroid hormone, but not to the initial parathyroid hormone peptide sequence [VAL-SER-GLU-ILE-GLN-LEU-MET (SEQ ID No. 1)].

(Amended) 19. The kit of Claim 18 also comprising [an] a second antibody specific for [the C-terminal portion of] any parathyroid hormone C-terminal fragment present in the sample.

(Amended) 20. A kit containing reagents for performing an assay for whole parathyroid hormone comprising:

- c) a first substantially pure antibody or antibody fragment specific for [the] an initial sequence of amino acids 1 to 7, (SEQ ID NO. 1), of whole parathyroid hormone which comprises a domain for adenylate cyclase activation, [VAL-SER-GLU-ILE-GLN-LEU-MET (SEQ ID No. 1)] wherein at least four amino acids in this sequence are part of [the] an antibody reactive portion of the peptide having a signal generating component attached thereto; and
- d) a second antibody that binds to whole parathyroid hormone, but not to the initial parathyroid hormone peptide sequence [VAL-SER-GLU-ILE-GLN-LEU-MET (SEQ ID No. 1)] which is bound to a solid support.

(Amended) 21. The kit of Claim 20 also comprising [an] a third antibody that specifically binds to an epitope left open after whole parathyroid hormone binds to the first antibody and the second

antibody, thereby forming a precipitating mass [specific for the C-terminal portion of parathyroid hormone].

(Amended) 22. A method for measuring the amount of functional N-terminal parathyroid hormone fragment and whole parathyroid hormone in a sample comprising:

- e) adding to the sample a first antibody or antibody fragment specific for [the] an initial peptide sequence of amino acids 1 to 7, (SEQ ID NO. 1), for whole parathyroid hormone which comprises a domain for adenylate cyclase activation[, VAL-SER-GLU-ILE-GLN-LEU-MET (SEQ ID No. 1)], wherein at least four amino acids in this sequence are part of [the] an antibody reactive portion of the peptide, in an amount sufficient to bind all functional N-terminal parathyroid hormone fragment and whole parathyroid hormone present;
- f) adding to the sample a second antibody or antibody fragment specific for [the] a peptide sequence of amino acids 28 to 34, (SEQ ID NO. 2), which comprises a domain for protein kinase C activation, wherein at least four amino acids in this sequence are part of the antibody reactive portion of the peptide, in an amount sufficient to bind all functional N-terminal parathyroid hormone fragment and whole parathyroid hormone present, at least the first antibody or the second antibody is labeled;
- g) allowing the first antibody and second antibody to bind to any N-terminal parathyroid hormone fragment or whole parathyroid hormone present, thereby forming a complex; and
- h) measuring the amount of labeled complex, and thereby determining the amount of whole parathyroid hormone.

(Amended) 23. A method for differentiating between a person having substantially normal parathyroid hormone function and having hyperparathyroidism comprising measuring whole parathyroid hormone [levels in the person].

(Amended) 24. A method for differentiating between a chronic uremia patient having substantially normal active parathyroid hormone levels and having hyperparathyroidism comprising measuring whole parathyroid hormone [levels in the person].